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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,054	11/08/1999	KEITH S. LOWE	0943	4699

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EXAMINER
IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
1638	11

DATE MAILED: 01/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/435,054	Applicant(s) LOWE ET AL.	
	Examiner Medina Ibrahim	Art Unit 1638	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group IA (claims 1-12, 15, 33, and 48-49), with traverse, in Paper No. 10 is acknowledged. The traversal is on the ground that the co-examination of Groups I-III would not an undue burden on the Examiner because the nucleic acids, their encoded polypeptides, and methods that employ at least one of the nucleic acids introduced into a plant are closely related. Applicants assert the Inventions I, II, II are independent or distinct. These arguments are considered and not found persuasive for the reasons of record. Inventions I, II, and III, as shown in the last Office action, are independent and patentably distinct inventions. There is no evidence in record that the three inventions are obvious over each other. In addition, both the literature and sequence search of Groups I-III are divergent , and searching them together will pose series burden on the Examiner, even if some of the search overlap. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Claims 1-61 are pending in this application.

Claims 1-12, 15, 33, and 48, 49, drawn to SEQ ID NO:1 encoding SEQ ID NO:2, are under examination.

Claims 13-14, 16-32, 34-47, and 50-61, and SEQ ID NO:7-23, are withdrawn from consideration as being drawn to a non-elected invention.

Sequence Listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS form 1449, Paper Nos. 4, 5 and 6 are attached to the instant Office action.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. See the attached Notice of Draftsperson.

Objections

The specification is objected to because of the following informalities: for example, page 39, line 19, and page 41, line 9, cite hyperlink which is directed to an Internet address. The use of hyperlinks is not permitted under USPTO current policy because the contents of such links are subject to a change. Therefore, New Matter might be a constant problem. The specification, page 39, lines 6 to 7 and page 59, lines 13-14, is also objected for reciting sequence without sequence identifier. Applicant must submit a new CRF and paper copy of the Sequence Listing, including said sequence. Applicant must also amend the specification to include the SEQ ID NO for these sequences.

Claims are objected for the following informalities: claims that recite non-elected inventions should be amended accordingly. Claims 15, 33, and 48-49 are objected to for depending non-elected inventions.

Claim Rejections - 35 USC § 112

2. Claims 1-12, 15, 33, and 48-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, part (f), is indefinite for failing to recite the specific hybridization conditions which define the claimed high stringency. In claim 1(b), what is "Vector nti Suite, InforMax Version 5. Dependent claims 2-12 and 15 are included in the rejection.

In claims 11 and 12 , "seed" should be changed to ---transgenic seed--- to clarify that the seed retains the heterologous nucleic acid of the parent plant.

Claim 3 recites "funtional equivalent" as it is unclear what is encompassed by the "functional equivalent" which is defined as a polynucleotide with a sufficient length to modulate level of LEC1 (page 6 of the specification). It is also unclear as to how the polynucleotide with a sufficient length would hybridize under undefined hybridization conditions. The metes and bounds of the claim are unclear.

Claims 33 and 48-49, recite " a responsive plant cell". The specification defines " a responsive plant cell" as " a plant with positive response" which is unclear as what is encompassed by the responsive plant. The metes and bounds of the claim are unclear.

Written Description

Claims 1-12, 15, 33, and 48-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. Claim 1, part (b), recites an isolated nucleic acid comprising a polynucleotide amplified from a plant nucleic acid library using specific primers. In addition, 1(b) recites "primers determined by using Vector nti Suite, InforMax Version 5" which may yield unrelated genes, depending on the parameters that this version uses. Also, part (d) recites " a plant HAP3-type ccaat-box transcriptional activator" which reads on any plant LEC1 gene which Applicant was not in possession at the time the application was filed. The specification does not disclose other than SEQ ID NO:1 encoding a LEC1 polypeptide. There are insufficient relevant identifying characteristics which would allow one skilled in the art to predictably determine what will be the structure of non-LEC1 polynucleotides which the claim encompasses. Therefore, the disclosure of SEQ ID NO:1, or the nucleotide sequence encoding SEQ ID NO:2, does not provide an adequate written description of non-LEC polynucleotides which can be amplified from a plant nucleic acid library using the recited primers. In view of the above considerations one skilled in the art would not recognize that Applicant was in possession of any polynucleotide amplified from a plant nucleic acid library using the specified primers. Thus, given the breadth of the claims which reads on genes yet to be discovered; and in view of level of knowledge and skill in the art, a person skilled in the art would not recognize from the disclosure that Applicant was in possession of polynucleotides encoding non-LEC1 polypeptides. Claims 33, and 48-49 are also included in the rejection because the claims encompass LEC1 polynucleotides from any source and it is unclear either from the specification or from the prior art whether that the consensus of SEQ ID NO:23 is common to all LEC1 polypeptides including

those from non-plant sources. Therefore, it is unclear if Applicants was in possession of any LEC1 polynucleotides at the time this application was filed.

Weighing all above factors, the written description requirement is not satisfied. See Written Description Requirement published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111).

Claim Rejections - 35 USC § 101 Utility

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-12 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility. The claims are drawn to a polynucleotide amplified from a plant nucleic acid library using specified primers, a polynucleotides having at least 60% sequence identity to SEQ ID NO: 1, or a ribonucleic acid sequence encoding a polypeptide having at least 60% sequence identity to SEQ ID No:2. No function is recited for these sequences. It is unclear what will be the utility of the non LEC1 polynucleotides amplifiable from a plant nucleic acid library using the specified primers. Applicants assert that a polynucleotide having 60% sequence identity to SEQ ID NO:1 would encode a polypeptide with LEC1 activity. Applicants further assert that a polypeptide having 60% sequence identity would have LEC1 activity. However, it is unclear what would be the utility of said polynucleotide or said polypeptide if the 40% lack of identity falls in region crucial for the

LEC1 activity. The prior art as exemplified by Bork et al teach that protein function can not be predicted based on sequence homology, especially where the sequence identity between the proteins is less than 70%. Bork (Genome Research, Vol. 10, 2000, pp. 398-400 (U)) teaches the pitfalls associated with comparative sequence analysis for predicting protein function because of known error margins for high-through put computational methods. Bork specifically teaches that computational sequence analysis is far from perfect, despite the fact that sequencing itself is highly automated and accurate (pp. 398, col. 1). One of the reasons inaccuracy is that the quality of data in public databases is still insufficient. This is particularly true for data relating to protein function. Protein function is context dependent, and both molecular and cellular aspects must be considered (pp. 398, col. 2). Conclusions from comparison analysis are often stretched with regard to protein products (pp. 398, col. 3). Furthermore, although gene annotation via sequence database searches is already routine, even here the error rate is considerable (pp. 399, col. 2). Most features predicted with an accuracy of greater than 70% are of structural nature and, at best, only indirectly imply certain functionality (pp. 399, Table 1 legend). As more sequences are added to databases and as errors accumulate and propagate, it becomes more difficult to infer correct function from the many possibilities revealed by a database search (pp. 399, paragraph bridging columns 2 and 3). Bork cautions that, although current methods seem to capture important features and define general trends, 30% of structure-function features are missing or predicted inaccurately. This must be kept in mind when processing the results (pp. 400, paragraph bridging columns 1 and 2). See, also Lazar et al (Molecular and Cellular Biology, March 1988, Vol. 8,

No. 3, pp. 1247-1252 (V)) teaches a mutation of aspartic acid 47 and leucine 48 of a transforming growth factor alpha results in different biological activities (Title). Broun et al (Science, 13 November 1998, Vol. 282, pp. 131-133 (W)) teaches as few as four amino acid substitutions can convert an oleate 12-desaturase activity (Abstract). Given Bork's, Broun, and Lazar's teachings; Applicants' failure to provide evidence that the claimed polynucleotides or polypeptide having 60% sequence identity to SEQ ID NO:1 or 2 respectively would have LEC1 function, the claimed invention lacks a credible asserted utility. See, Utility Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Claims 1-12 and 15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention without undue experimentation. The specification is not enabling any polynucleotide, other than SEQ ID NO:1, amplified from a plant nucleic acid library using the specified primers. The specification does not disclose a polynucleotides having at least 60% sequence identity to SEQ ID NO: 1 and still encoding LEC1 polypeptide. The specification does not disclose a ribonucleic acid sequence encoding a polypeptide having at least 60% sequence identity to SEQ ID No:2 that still retains LEC1 activity. Applicants should note that the polynucleotide of claim 1 (i) would not hybridize to polynucleotide of (a) and (g) because of codon degeneracy. Further the specification is not enabling a polynucleotide with 20-contiguous bases of SEQ ID NO:1 encoding a polypeptide having LEC1 activity. See, Shen et al (attached

Sequence Search Result, Accession no. Y11210, 1997) who teach 26 contiguous bases of SEQ ID NO:1 with no LEC1 activity.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 15, and 48-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Harada et al US 6,235, 975, filed June 24, 1998 (A)). The claims are directed to an isolated nucleic acid having at least 20 contiguous basis of SEQ ID NO:1 encoding an LEC1 polypeptide with at least or a hybridizing sequence thereof with at least 25 nucleotides in length which is a functional equivalent a transgenic male sterile plant produced by inducing apomixis in a responsive plant cell by introducing an LEC1 polynucleotide into said plant cell, and growing the plant cell to produce somatic embryo. Harada et al teach isolated nucleic acid sequence with 66 contiguous bases and 66 nucleotides in length of SEQ ID NO:1 (see attached Sequence Search Result, pages 3-4) encoding an LEC1 polypeptide with, an expression vector comprising a plant promoter, sense or antisense expression of said LEC1 nucleic acid molecule, transformation and growth of responsive plant cells (as defined in page 6, lines 20-25 of Applicant's specification)

with an LEC1 nucleic acid molecule to induce embryo formation in vegetative cells, and transgenic plants with a desired trait (see columns 22-30). Induction of apomixis and the resultant male-sterile plants are inherent properties of plants expressing LEC1 polypeptides.

Claims 1-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Boudet et al (US 5,451, 514).

The scope of the claims encompasses a sequence which is not fully complementary with the nucleotide sequence of SEQ ID NO:1, and would read on a 2-mer polynucleotide (claim 1, part (I)). The scope of 1(f) does not require that the 25 nucleotides be contiguous, and no hybridization conditions are recited..

Boudet et al teach an isolated nucleic acid sequence which would inherently comprise the claimed complementary polynucleotide of SEQ ID NO:1. Vector, chimeric construct, plant/cell/seed are also disclosed. The reference also teaches the claimed 25 nucleotides of SEQ ID NO:1 which would also hybridize thereto, since the 25-nucleotides does not require to be contiguous (see, column 13, Example 16) .

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-12, 15, 33, 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al US 6,235, 975, filed June 24, 1998(A)) in view of Lotan et al (Cell, vol. 93, pp. 1195-1205, June 1998 (Applicant's IDS).

Claims are drawn to an isolated nucleic acid comprising a polynucleotide or ribonucleic acid encoding an LEC1 polypeptide, and transgenic plants including male-sterile plants produced by introducing non-Arabidopsis LEC1 polynucleotide into a non-Arabidopsis and responsive plant cell to induce somatic embryo or apomixis in said plant cell and growing the plant cell under conditions sufficient to stimulate production of a transformed embryo.

Harada et al teaches methods for isolation and use of LEC1 nucleic acid molecule to transform plant cells to induce embryo development and for a desired trait as discussed above. In column 21, lines 32-45, Harada et al teach that the LEC1 nucleic acids can be transformed with any plant to confer desired traits.

Harada et al do not teach non-Arabidopsis LEC1 gene.

Lotan et al teach the importance of LEC1 genes to regulate transcription of genes required for both embryo morphogenesis and cellular differentiation in higher plants (page 1196, column 1, last paragraph). Lotan discloses " LEC1 is the only gene shown to be sufficient to induce embryo development and act specifically during embryogenesis to control both the morphogenesis and maturation phases" (page 1195, column 2, last sentence of the first full paragraph; paragraph bridging pages 1202 and 1203). Therefore, it would have been obvious to one having ordinary skill in the art at the time invention was made to utilize the method of isolating and using LEC1 nucleic acid to transform with plants as taught by Harada et al, and to modify that method by incorporating the plant LEC1 gene of Harada as taught by Lotan et al, to produce transformed plant/seeds with a desired trait, with a reasonable expectation of success. One skilled would have been motivated to do so because of the importance of the LEC1 genes to regulate embryo development in higher plants as taught by Lotan et al. Thus, the claimed invention as whole was clearly *prima facie* obvious.

Remarks

8. No claim is allowed.

9. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The

Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

December 24, 2001
mai

P Phuong Bui

PHUONG T. BUI
PRIMARY EXAMINER

12/31/01

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.